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| EXAMINER | |
|---|---|
| LOCKARD, JON MCCLELLAND | |
| **ART UNIT** | **PAPER NUMBER** |
| 1647 | |

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/855,828 | CREECH ET AL. | |
| | Examiner | Art Unit | |
| | Jon M. Lockard | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-4,6,7,18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,7,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/1/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of Application, Amendments, and/or Claims*

1. The Amendment filed 04 February 2005 has been received and entered in full. Claims 1, 2, and 7 have been amended and claims 5 and 8-17 have been cancelled. Therefore, claims 1-4, 6-7, and 18-19 are pending and claims 1-4, 6-7, and 18-19 are the subject of this Office Action.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Information Disclosure Statement*

3. The information disclosure statement (IDS), filed 01 April 2005, has been considered by the examiner.

### *Withdrawn Objections and/or Rejections*

3. The objection to the Specification as set forth at page 3 (¶6) in the previous Office Action (mailed 02 November 2004) is withdrawn in view of Applicant's amendments (filed 04 February 2005).

4. The rejection of claims 5 and 8-9 under 35 U.S.C. § 101 and 35 U.S.C. § 112 as set forth at pages 4-12 (¶7-26) in the previous Office Action (mailed 02 November 2004) is moot in view of Applicants cancellation of said claims (filed 04 February 2005).

5. The rejection of claims 1-9 and 18-19 under 35 U.S.C. §112 ¶2 as set forth at pages 12-13 (¶27-30) in the previous Office Action (mailed 02 November 2004) is withdrawn in view of Applicant's amendment of claims 1, 7, and cancellation of claim 8 (filed 04 February 2005).

## *Maintained Objections and/or Rejections*

### *Drawings*

6. Applicants are advised that upon issuance of a patent, the complete text of the sequence listing submitted in compliance with 37 C.F.R.§§1.821-1.825 will be published as part of the patent. Therefore, it is unnecessarily redundant to repeat the sequence information in the form of Figures. Applicants should amend the specification to delete any Figures (e.g. Figures 2-4) which consist only of nucleic acid or protein sequences which have been submitted in their entirety in computer readable format (i.e. as SEQ ID NO:'s) and should further amend the specification accordingly to reflect the replacement of the Figure by the appropriate SEQ ID NO:.

### *Claim Rejections - 35 USC § 101*

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-4, 6-7, and 18-19 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well

established utility, for reasons set forth in the previous Office Action (mailed 02 November 2004).

9. Claims 1-4, 6-7, and 18-19 are drawn to a putative subunit of a cyclic nucleotide gated cation channel, human CNG3B protein (SEQ ID NO:1), the nucleic acids encoding the protein (SEQ ID NO:2 and SEQ ID NO:3) and a method of producing the protein. The claimed invention is not supported by either a specific and substantial asserted utility, or a well-established utility. A specific and substantial utility is one that is particular to the claimed subject matter and that identifies a "real world" context of use for the claimed invention which does not require further research.

10. Applicants citation of relevant case law at pages 6-7 of the response is noted. The Examiner takes no issue with the case law. Rather, the issue here is that there is not a single specific, substantial utility for the claimed nucleic acids, nor dies the nucleic acid or the protein that is encoded by it posess a well-known utility. The Applicants argue at page 8 that cyclic nucleotide-gated cation channels play an important role in regulating intracellular cation concentration, e.g., $Ca^{+2}$ concentration, which can act as a second messenger to regulate a number of cellular events and therefore affect the biological functions of the tissue in which the cation channels are expressed. The Applicants then assert, that since the CNG3B nucleic acids of the instant application (SEQ ID NO:1 and SEQ ID NO:3) are expressed in retina and testis, modulators of the CNG3B channel can be expected to be useful for treating diseases or conditions in the retina and testis, such as vision problems and male infertility. The applicants have submitted references published after the effective filing date of the Instant Application which confirm that the CNG3B polypeptide encoded by the claimed nucleic acids (SEQ ID NO:2

and SEQ ID NO:3) is a subunit of a cyclic nucleotide-gated cation channel, which the studies disclose is implicated in a particular form of color blindness (See Exhibits A-C). The Applicants then argue at pages 9-10 that the Specification teaches methods of identifying said modulators of CNG3B. The Applicants argue at page 10 that the Specification discloses specific utility in that a "disease condition", i.e., altered cytoplasmic cation concentration, that correlates with a "biological activity", i.e., the opening and closing of the CNG3B channels. The Applicants argue at page 11 that the present invention has a substantial or "real-world" use since the Specification teaches that CNG3B channels modulate intracellular cation concentration in certain tissues and teaches how to assay the function of a CNG3B channel and how to identify modulators of the CNG3B channels. The Applicants then argue at page 10 that the asserted utility of the present invention is credible. Applicant's arguments filed have been fully considered but they are not persuasive for the following reasons. The assays taught by the Specification are not specific for this particular subunit of a cyclic nucleotide-gated cation channel and could be performed with any subunit or any cation channel. Furthermore, the Specification as filed has not taught any "modulators" of the CNG3B subunit, or whether inhibition or promotion of the CNG3B subunit is required for treatment of vision problems or male infertility. Lastly, even though cytoplasmic $Ca^{+2}$ is linked to several diseases, the instant Specification does not teach any specific disease state that is associated with the claimed CNG3B subunit of SEQ ID NO:1 that is encoded by SEQ ID NO:2 and SEQ ID NO:3. This can only be accomplished through additional extensive experimentation, a fact which is confirmed by the studies of Kohl et al. (Exhibit A), Peng et al. (Exhibit B), and Peng et al. (Exhibit C). While the Applicants assert that CNG3B polynucleotides are expressed in the retina and therefore

modulators of CNG3B could be used to treat "visual disorders", there is nothing in the Specification as originally filed that would lead the skilled artisan to color blindness. Therefore, the evidence submitted by the Applicants (Exhibits A-C) is not commensurate in scope with the original assertion of utility. Thus, this asserted utility is neither specific nor substantial. The question of "real-world" utility is not relevant as the asserted utility is credible, therefore it is a "real-world" utility. However, it is not specific or substantial, and these can only be established through additional extensive experimentation. Thus this asserted utility, while credible, is neither specific nor substantial.

11. The Applicants argue at pages 11-14 that the Examiner does not believe the asserted utility of the claimed nucleic acids encoding CNG3B. The Examiner does not dispute the credibility of the asserted utility. While it is credible that CNG3B (SEQ ID NO:1) is a B subunit of a cyclic nucleotide-gated cation channel, its identification as such is not sufficient to establish either a well known, or a specific, substantial utility for the claimed nucleic acids (SEQ ID NO:2 and SEQ ID NO:3 that encode the CNG3B polypeptide (SEQ ID NO:1).

12. The Applicants argue at pages 14-16 that the claimed CNG3B channels are fully characterized both structurally and functionally, and reviews the PTO's "Revised Interim Utility Guidelines Training Materials" to support this argument. The Examiner would like to point out that what is claimed is a subunit of a cyclic nucleotide-gated channel, not the channel itself. The Examiner does not agree with the comparison given. Moreover, the fact pattern presented in Example 8 of the "Guidelines" is not analogous to the Instant Application. Wherein enzymes have a well-established utility, and XYZ is a well-known enzyme, the claims in the Instant Application are drawn to a subunit of a cyclic nucleotide-gated cation channel, which have no

well-established utility. Furthermore, compound A in example 8 is directed to a compound that "inhibits" an enzyme. The Instant Application only teaches that compounds which "modulate" CNG3B can be used to treat visual disorders or male infertility, and further extensive experimentation would be required of the skilled artisan to determine whether compounds that inhibit CNG3B could be used in methods of treatment, or whether compounds that potentiate/promote CNG3B could be used in treatment methods.

13. The Applicants argue at pages 16-17 that the present situation is analogous to the situation presented in *Nelson v. Bowler.* Moreover, the fact pattern presented in Example 8 of the "Guidelines" is not analogous to the Instant Application. In *Nelson v. Bowler*, the claimed compound was a pharmaceutical, which had been shown to have a physiological effect (change in blood pressure) in a whole animal. The instant claims are drawn to nucleic acids encoding a subunit of a cyclic nucleotide-gated cation channel for which no known physiological function has been correlated, other than regulating intracellular cation concentration.

***Claim Rejections - 35 USC § 112, 1st Paragraph (Enablement)***

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 1-4, 6-7, and 18-19 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and

credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to make/use the claimed invention.

16. Furthermore, even if the nucleic acid molecules of SEQ ID NOs:2 and 3, or the amino acid encoded by them (SEQ ID NO:1) were to have a patentable utility, the instant disclosure would not be found to be enabling for the full scope of the claimed invention for reasons set forth at pages 8-10 (¶ 16-19) in the previous Office Action (mailed 02 November 2004).

17. Claims 1, 2, and 7 are drawn to a genus of nucleic acid molecules encoding a polypeptide comprising an amino acid sequence having at least 85%, 90%, or 95% sequence identity to SEQ ID NO:1. However, other than the protein of SEQ ID NO:1 and the DNA molecules of SEQ ID NO:2 and SEQ ID NO:3 that encode the protein, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims as set forth at pages 8-10 (¶ 16-19) in the previous Office Action (mailed 02 November 2004).

18. The Applicants traverse the rejection of claims 1, 2, and 7 at pages 17-19 of the response on the grounds that the specification discloses two nucleic acid sequences set forth as SEQ ID NO:2 and 3 which encode the polypeptide of SEQ ID NO:1, and a method of how to screen for CNG3B polypeptide (SEQ ID NO:1) variants having the biological activity as recited in the claims. The Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

19. The specification's disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without undue experimentation. The factors listed below have been considered in the analysis of enablement:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

20. The claims are drawn to isolated polynucleotides that encode a protein that share at least 85%, 90%, or 95% sequence identity to SEQ ID NO:1. However, the disclosure has not shown (1) which portions of the protein encoded by SEQ ID NOs: 1 and 3 are critical to the activity of the CNG3B polypeptide of SEQ ID NO:1; (2) what modifications e.g., substitutions, deletions, or additions) one can make to SEQ ID NO:2 or SEQ ID NO:3 that will result in protein mutants or variants with the same function/activity as the claimed CNG3B protein of SEQ ID NO:1; and (3) any guidance on how to use mutants or variants of SEQ ID NO:1 which would, based on the language of said claims, encompass both active and inactive variants of SEQ ID NO:1, or the nucleic acids that encode the aforementioned peptides. While the Applicants have argued that the Specification teaches how to screen the large number of variants encompassed by the claims to identify those having the biological activity recited in the claims (See page 18, ¶2 of the response filed 04 February 2005), the requirement of 35 U.S.C. § 112(1) enablement is to "enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to *make* and *use*", not *make* and *test*.

21. The state of the art is such that the relationship between the sequence of a protein and its activity is not well understood and unpredictable, and that certain positions in the sequence are critical to the protein's structure/function relationship. The problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. More importantly, certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions [see Wells (1990) "Additivity of Mutational Effects in Proteins." Biochemistry **29**(37): 8509-8517; Ngo *et al.* (1995) "The Protein Folding Problem and Tertiary Structure Prediction, Chapter 14: Computational Complexity Protein Structure Prediction, and the Levinthal Paradox" pp. 492-495]. However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. Although the specification outlines art-recognized procedures for producing and screening for active variants, this is not adequate guidance as to the nature of active derivatives that may be constructed, but is merely an invitation to the artisan to use the current invention as a

starting point for further experimentation. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity.

22. Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

23. It was found in Ex parte Maizel (27 USPQ2d 1662 at 1665) that:

> Appellants have not chosen to claim the DNA by what it is but, rather, by what it does, i.e., encoding either a protein exhibiting certain characteristics, or a biologically functional equivalent thereof. Appellants' claims might be analogized to a single means claim of the type disparaged by the Court of Customs and Patent Appeals in In re Hyatt, 708F.2d 712, 218 USPQ 195 (Fed. Cir. 1983). The problem with the phrase "biologically functional equivalent thereof" is that it covers any conceivable means, i.e., cell or DNA, which achieves the stated biological result while the specification discloses, at most, only a specific DNA segment known to the inventor. Clearly the disclosure is not commensurate in scope with the claims."

***Claim Rejections - 35 USC § 112, 1st Paragraph (Written Description)***

24. Claims 1, 2, and 7 also remain rejected under 35 USC 112, first paragraph for the reasons already of record on pages 10-12 (¶ 21-26) of the previous Office Action (mailed 02 November

2004), as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

25. The specification discloses two nucleotide sequence set forth as SEQ ID NO:2 and SEQ ID NO:3, which encode a polypeptide of SEQ ID NO:1. However, claims 1, 2, and 7, as written, recite a genus of nucleic acid molecules encoding a polypeptide comprising an amino acid sequence having at least 85%, 90%, or 95% sequence identity to SEQ ID NO:1. Thus, the claims are drawn to a genus of DNA molecules which encompass a large number of nucleic acids that vary substantially, both in length and in nucleotide composition.

26. The Applicant traverses the rejection of claims 1, 2, and 7 on the grounds that instant claims provide both functional features, e.g., encoding a CNG3B polypeptide capable of forming a cyclic nucleotide-gated cation channel with at least one alpha subunit, and structural features, e.g., comprising a subsequence having at least 85% sequence identity to SEQ ID NO:1. The Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

27. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. In this case, the only factor present in the claims is a mere chemical property of the DNA in the form of a recitation of percent identity and

the desired functional characteristic of "forming, with at least one alpha subunit, a cation channel having the characteristic of cyclic nucleotide gating". The specification does not identify any particular structure/function correlation or biological activity. The distinguishing characteristics of the claimed genus are not described. The only adequately described species are the nucleic acid sequences represented by SEQ ID NOs:2 and 3 and the polypeptide encoded by SEQ ID NOs:2 and 3 set forth as SEQ ID NO:1. Accordingly, the specification does not provide adequate written description of the claimed genus.

28. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

29. With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides and DNA molecules, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

30. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to

lack of written description for that broad class. The specification provided only the bovine sequence.

31. Therefore, only the polynucleotide that encodes the CNG3B polypeptide of SEQ ID NO:1 and the DNA molecules of SEQ ID NO:2 and SEQ ID NO:3, but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

***Summary***

32. No claim is allowed.

33. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback**, can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML
April 28, 2005

ROBERT S. LANDSMAN, PH.D
PRIMARY EXAMINER